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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,730	10/19/2001	Paul Arthur Mason	10071-018-999	9664
20583	7590	06/15/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			GHALI, ISIS A D	
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 06/15/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/045,730	Applicant(s) MASON, PAUL ARTHUR	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-22 and 24-61 is/are pending in the application.
- 4a) Of the above claim(s) 7-11, 17-21 and 28-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6, 12-16, 22, 24-27 and 54-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' amendment, filed 03/26/2004.

Claims 2 and 23 have been canceled, and claims 54-61 have been added.

Claims 1, 3-6, 12-16, 22, 24-27, 54-61 are included in the prosecution.

Election/Restrictions

1. This application contains claims 7-11, 17-21, 28-53 drawn to an invention nonelected with traverse in the reply filed on 04/25/2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The following rejections were discussed in details in the previous office action, and maintained for reasons of record:

Claim Rejections - 35 USC § 102

2. Claims 1, 3-6, 22, 24-27, 56 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,455,066 ('066).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '066 disclosed patch comprising permeable backing (breathable), and a carrier formulated with at least one local anesthetic (col.8, lines 4-6; col.9, lines 11, 18, 64-65). The carrier comprises polyvinyl pyrrolidone hydrogel (col.8, lines 27-28; 67). The preferred local anesthetic is lidocaine (col.5, lines 30-39). The formulation comprises preservatives (col.6, line 57). The backing is derived from polyester (col.9, lines 12-13). The patch is used for local anesthetization of skin prior to minor surgical procedures (col.11, lines 28-29). The anesthetic forms 0.5 to 12% of the formulation (col.9, lines 64-67).

3. Claims 1, 3-6, 12-16 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,469,227 (227).

US '227 disclosed a non-occlusive adhesive skin patch used to relieve topical discomfort (abstract; col.2, lines 5-8). The patch comprises a breathable backing of polyester coated with a therapeutic formulation (col.3, lines 7-16, 35-36, 42, 50-56). The patch is packaged (col.4, line 1; col.18, lines 45-47). The therapeutic formulation is hydrogel that comprises local anesthetic such as lidocaine, and polymer such as polyvinyl pyrrolidone (col.4, lines 13-15, 28, 45; col.7, lines 1-2; col.11, lines 43-45). The

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patch further comprises alcohol, which reads on the preservative (col.6, line 6). The examples shows that the amount of anesthetic ranges from 1-4%.

4. Claims 1, 3-6, 22, 24-27 are rejected under 35 U.S.C. 102(e) as being anticipated by PGPB 2003/0027833 ('833).

PGPB '833 disclosed a method and a delivery system for administration of at least one local anesthetics agent to a patient by applying the delivery system to the skin (abstract; page 2, 0017, 0019). The drug delivery device comprises a backing layer laminated to a drug reservoir (page 2, 0023; page 8, 0088). The reservoir comprises a hydrogel comprising hydrophilic polymers comprising polyvinyl pyrrolidone (page 6, 0070, 0071; page 8, 0086; page 9, 0091). The reservoir comprises the local anesthetic and a preservative (page 8, 0083). The backing layer is preferably breathable and made of polyester or polyether (page 9, 0092). The preferred local anesthetic is lidocaine (page 4, 0048).

Response to Arguments

5. Applicant's arguments filed 03/26/2004 have been fully considered but they are not persuasive.

The main gist of applicant's argument against 102 rejections above is that the references do not teach sterile patch.

In response to the above argument, the examiner position is that the claims are directed to product and method of its use and all the element of the product and its use

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are disclosed by the cited reference. Further, all the elements of the product and the method of its use are recited in the body of the claim, and the permeable is not essential to understand limitations or terms in the claim body and does not provide antecedent basis for terms in the body of the claim. The recitation of the limitation "sterile" in the claim permeable does not limit the scope of the claim since such statement does not read in the context of the entire claim, and the body of the claim defined the subject matter of the claimed invention.

The following new ground of rejection is necessitated by applicant's amendment:

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 57 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 contains multiple trade names for PEG. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of

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goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe PEG and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

8. Claims 1, 3-6, 12-16, 22, 24-27, 54-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '227 in view of US '366.

The teachings of US '227 and US '366 are discussed above.

However, US '227 does not teach that the patch is sterile, the amount of PVP and the anesthetic, species of the species of different ingredients.

The amounts of different ingredients and specific species are not considered critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

US '366 teaches a non-stingy adhesive hydrogel that can be formed into patches for long term application of a pharmaceutically active agents to a patient and having both adhesive and cohesive properties (abstract; col.4, lines 30-31). The patches delivered by the hydrogel are sterile and their packaging should be adaptable to ensure sterility (col.5, lines 36-55). The patch must be sterile and the patch and the associated structural and packaging material are sterilized (col.5, lines 35-55). The hydrogel comprises polyvinyl pyrrolidone (col.6, lines 35-37, 47-49). The hydrogel further

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comprises preservative and anesthetics (col.8, lines 5, 10). The hydrogel is coated on a backing of polyester (col.9, lines 1-13).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the patch comprising polyvinyl pyrrolidone hydrogel and local anesthetic as disclosed by US '227 and sterilize the patch as disclosed by US '366, motivated by the teaching of US '366 that the patch must be sterile and that the patch and the associated structural and packaging material all can be sterilized, with reasonable expectation of having a sterile patch that deliver local anesthetic to the skin of the patient in need with success.

9. Claims 1, 3-6, 12-16, 22, 24-27, 54-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over PGPB '833 in view of US '366.

The teachings of PGPB '833 and US '366 are discussed above.

However, PGPB '833 does not teach the patch is sterile, as claimed in claims 2 and 23, or packaged as claimed in claims 12-16. US '833 does not teach the amount of the ingredients and their claimed species.

The amounts of different ingredients and specific species are not considered critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the patch comprising polyvinyl pyrrolidone hydrogel and

local anesthetic as disclosed by PGPB '833 and package the patch and sterilize it as disclosed by US '366, motivated by the teaching of US '366 that the patch must be sterile and that the packaging ensures sterility, and also that the patch and the associated structural and packaging material all can be sterilized, with reasonable expectation of having a sterile patch that deliver local anesthetic to the skin of the patient in need with success.

Response to Arguments

10. Applicant's arguments filed 03/26/2004 have been fully considered but they are not persuasive.

Applicant traverses the above 103 rejections by arguing that the references do not teach sterile patch. The references do not teach the claimed composition and amounts. Cleary's composition requires permeation enhancer, monohydric alcohol, and non-liposomal carrier and Cooke's composition can include adhesive and humectants. Further Cooke's reference teaches PVP in a long list and is not the preferred polymer. The combination of Cleary or Cooke with Fox would not have had a reasonable expectation of success in achieving the present invention. The examiner's rejection could be only based on impermissible hindsight.

In response to the argument regarding the teaching of the patch as sterile, the examiner position is that the claims are directed to product and method of its use and all the element of the product and its use are disclosed by the cited reference. Further, all the elements of the product and the method of its use are recited in the body of the

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claim, and the permeable is not essential to understand limitations or terms in the claim body and does not provide antecedent basis for terms in the body of the claim. The recitation of the limitation "sterile" in the claim permeable does not limit the scope of the claim since such statement does not read in the context of the entire claim, and the body of the claim defined the subject matter of the claimed invention.

Each of the cited primary references all teaches patch comprising composition comprising PVP, local anesthetic, PEG, and acrylic polymer, US '227, col.4, lines 41-56; col.7, lines 1-2, 35-41, 54-60; and US '833 page 2, 0017; page 4, 0048; page 6, 0070, 0071; page 7, 0079; page 11, claim 10. The secondary reference is relied upon for the solely teaching of the sterile patch, and it does not have to teach the composition of the patch. The amounts of different ingredients are not considered critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

The expression "comprising " permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive, even in major amounts. See *Moleculon Research Corporation v CBS, Inc.* 229 USPQ 805, *In re Baxter* 210 USPQ 795, 803. Thus, the claim language permits the presence of permeation enhancer, monohydric alcohol, and non-liposomal carrier as disclosed by Cleary's, and permits adhesive and humectants as disclosed by Cooke's.

Regarding applicant's argument that the Cooke disclosed PVP in a long list and is not the preferred polymer, the examiner position is the use of patents as references is

not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332—33, 216 USPQ 1038, 1039 (Fed. Cir. 1983). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the secondary reference suggests the sterile patch and showed that the sterile is recognized in the transdermal art.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was

within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

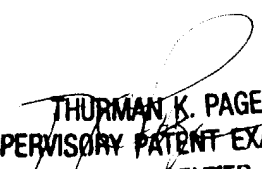
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615


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